

AMENDMENTS TO THE CLAIMS

1. (Currently amended) Microparticulate oral pharmaceutical dosage form for the delayed and controlled release of at least one active principle (AP) --excluding perindopril--this active principle having an absorption window in vivo that is essentially limited to the upper parts of the gastrointestinal tract,

wherein the dosage form comprises "reservoir" microcapsules of active principle, each coated with at least one coating film,

wherein the coating film comprising at least one hydrophilic polymer A carrying groups that are ionized at neutral pH, and at least one hydrophobic compound B;

wherein the at least one hydrophobic compound B is selected from the group consisting of the products which tradenames (trademarks) are the following: Dynasan, Cutina, Dub, Castorwax, Croduret, Compritol, Sterotex, Lubritab, Apifil, Akofine, Softisan, Super Hartolan, Protalan, Akosoft, Akosol, Cremao, Massupol, Novata, Suppocire, Wecobee, Witepsol, Lanolin, Ineromega, Estaram, Suppoweiss, Gelucire, Precirol, Emulcire, Plurol diisostearique, Geleol, Hydriene and Monthyle; hydrogenated palm oil, hydrogenated castor oil, hydrogenated soybean oil, glyceryl behenate, hydrogenated cottonseed oil, wax yellow, lanolin, anhydrous milk fat, hard fat suppository base, omega 3 fatty acids, lauroyl macrogolglycerides, glyceryl palmitostearate, cetyl alcohol, polyglyceryl diisostearate and glyceryl stearate; and

wherein the release of the active principle is governed by two different triggering mechanisms,

wherein the first triggering mechanism releases the at least one AP based on a variation in pH and

wherein the second triggering mechanism releases the at least one AP after a predetermined residence time in the stomach,

wherein the dissolution behavior of the pharmaceutical dosage in vitro is such that: at a constant pH of 1.4, the dissolution profile includes a latency phase with a duration less than or equal to 5 hours, and the change from pH 1.4 to pH 6.8 results in a release phase that starts without a latency period.

2. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the dissolution profile includes a latency phase with a duration of between 1 and 5 hours.

3. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein

wherein the mass fraction of the coating film (% by weight, based on the total mass of the microcapsules) of ≤ 40 ;

wherein said microcapsules have a diameter below 2000 microns,

wherein the weight ratio B/A is between 0.45 and 1.0, and

wherein the hydrophobic compound B is crystalline in the solid state and has a melting point T_B such that $T_B \geq 40^\circ \text{C}$.

4. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the microcapsules have a diameter of between 200 and 800 microns, wherein the weight ratio B/A is between 0.5 and 1.0 and wherein the hydrophobic compound B is selected from products that are crystalline in the solid state and have a melting point T_B such that $40^\circ \text{C} \leq T_B \leq 90^\circ \text{C}$.

5. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the at least one hydrophilic polymer A is selected from the group consisting of: (meth)acrylic acid polymers, alkyl (meth)acrylate polymers, (meth)acrylic acid/alkyl (meth)acrylate copolymers, cellulose derivatives, cellulose acetate, phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate, succinate; and mixtures thereof.

6. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the at least one hydrophilic polymer A is selected from the group consisting of: (meth)acrylic acid/ methyl(meth)acrylate copolymers, cellulose acetate, phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate, succinate; and mixtures thereof.

7. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the at least one compound B further comprises a compound selected from the group consisting of: vegetable waxes, hydrogenated vegetable oils, monoesters of glycerol with at least one fatty acid, diesters of glycerol with at least one fatty acid, triesters of glycerol with at least one fatty acid, glycerol esters of behenic acid, and mixtures thereof.

8. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the at least one compound B further comprises a second compound selected from the group consisting of: vegetable waxes, hydrogenated vegetable oils, at least one monoester of glycerol with at least one fatty acid, at least one diester of glycerol with at least one fatty acid, at least one triester of glycerol with at least one fatty acid; and mixtures thereof.

9. (Currently amended) The pharmaceutical dosage form according to claim 7 wherein said second compound is selected from the group consisting of: hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil, glyceryl behenate, hydrogenated castor oil, tristearin, tripalmitin, trimyristin, wax yellow, suppository bases, hard fat, anhydrous milk fat, lanolin, glyceryl palmitostearate, glycerylstearate, lauryl macroglycerides, cetyl alcohol, polyglyceryl diisostearate, diethylene glycol monostearate, ethylene glycol monostearate, ~~Omega-3~~ omega 3 fatty acids and any mixtures thereof.

10. (Previously Presented) The pharmaceutical dosage form according to claim 7 wherein said second compound is selected from the group consisting of: hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil, glyceryl behenate, hydrogenated castor oil, tristearin, tripalmitin, trimyristin and any mixtures thereof.

11. (Canceled).

12. (Canceled).

13. (Previously Presented) The pharmaceutical dosage form according to claim 3 wherein the coating film of the microcapsules is free from talc.

14. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein, at a constant pH of 1.4, the controlled release phase following the latency phase is such that the release time for 50% of the active principle ($t_{1/2}$) is defined as follows (in hours): $0.25 \leq t_{1/2} \leq 35$.

15. (Previously Presented) The pharmaceutical dosage form according to claim 1, characterized in that the release phase following the change from pH 1.4 to pH 6.8, which takes place without a latency period, is such that the release time for 50% of the AP ($t_{1/2}$) is defined as follows (in hours): $0.25 \leq t_{1/2} \leq 20$.

16. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the microcapsules comprise a single composite coating film AB.

17. (Previously Presented) The pharmaceutical dosage form according to claim 3, wherein the active principle is deposited on a neutral core with a diameter of between 200 and 800 microns.

18. (Presently Presented) The pharmaceutical dosage form according to claim 3, wherein the neutral core contains sucrose and/or dextrose and/or lactose.

19. (Previously Presented) The pharmaceutical dosage form according to claim 18, wherein the neutral core is a cellulose microsphere.

20. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the at least one active principle is selected from the group consisting of: antiulcer agents, antidiabetics, anticoagulants, antithrombics, hypolipidemics, antiarrhythmics, vasodilators, antiangina agents, antihypertensives, vasoprotectors, fertility promoters, labor inducers and inhibitors, contraceptives, antibiotics, antifungals, antivirals, anticancer agents, anti-

inflammatories, analgesics, antiepileptics, antiparkinsonian agents, neuroleptics, hypnotics, anxiolytics, psychostimulants, antimigraine agents, antidepressants, antitussives, antihistamines and antiallergics.

21. (Previously Presented) The pharmaceutical dosage form according to claim 20, wherein the active principle is selected from the group consisting of amoxicillin, metformin, acetylsalicylic acid, pentoxifyllin, prazosin, acyclovir, nifedipine, diltiazem, naproxen, ibuprofen, flurbiprofen, ketoprofen, fenoprofen, indomethacin, diclofenac, fentiazac, estradiol valerate, metoprolol, sulpiride, captopril, cimetidine, zidovudine, nicardipine, terfenadine, atenolol, salbutamol, carbamazepine, ranitidine, enalapril, simvastatin, fluoxetine, alprazolam, famotidine, ganciclovir, famciclovir, spironolactone, 5-asa, quinidine, morphine, pentazocine, paracetamol, omeprazole, metoclopramide and mixtures thereof.

22. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein said pharmaceutical dosage form is selected from the group consisting of: a tablet, a powder and a gelatin capsule.

23. (Canceled).

24. (Previously Presented) The pharmaceutical dosage form according to claim 1 which is a tablet that disperses in the mouth.